CLAIMS

What is claimed is:

1. A method for performing a lateral flow assay comprising:
    a. depositing a sample on a test strip at an application region, the test strip including a first detection zone with a first measurement zone;
    b. detecting a first detection signal arising from the first detection zone; and
    c. generating a baseline for the first detection zone by interpolating between values of the first detection signal outside of the first measurement zone and inside of the first detection zone.
2. The method of claim 1, wherein the first measurement zone comprises a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip.
3. The method of claim 1, further comprising locating a beginning boundary and an ending boundary for the first measurement zone on the test strip.
4. A method for performing a lateral flow assay comprising:
    a. depositing a sample on a test strip at an application region, the test strip including a second detection zone within a second measurement zone;
    b. detecting a second detection signal arising from the second detection zone; and
    c. generating the baseline for the second detection zone by interpolating between values of the second detection signal outside of the second measurement zone and inside of the second detection zone.

5. The method of claim 4, wherein the second measurement zone comprises a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip.

6. The method of claim 4, further comprising locating a beginning boundary and an ending boundary that defines the second measurement zone on the test strip.

7. The method of claim 6, further comprising:

   a. depositing a sample on a test strip at an application region, the test strip including a third detection zone with a third measurement zone;

   b. detecting a third detection signal arising from the third detection zone; and

   c. generating the baseline for the third detection zone by interpolating between values of the third detection signal outside of the third measurement zone and inside of the third detection zone.

8. The method of claim 7, wherein the third measurement zone comprises a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip.

9. The method of claim 7, further comprising locating a beginning boundary and an ending boundary that define the third measurement zone on the test strip.

10. The method of claim 4, including quantifying the first and second detection signal of the first and second detection zone with respect to the baseline.

11. The method of claim 10, including quantifying the third detection signal of the third detection zone with respect to the baseline.

12. The method of claim 10, comprising additional steps of

comparing the first detection signal quantified from the first detection zone with the second detection signal quantified from the second detection zone.

13. The method of claim 11, including evaluating the first detection signal quantified in the first measurement zone on a curve defined by the second and third detection signal quantified from the second and third measurement zones.

14. The method of claim 11, wherein the first measurement zone is formed from the concentration of compounds in an analyte binding zone on the test strip, and the second and third measurement zones are formed from the concentration of compounds in a control zone on the test strip.

15. The method of claim 7, wherein the detection signals arising from the detection zones is a light intensity.

16. The method of claim 15, wherein detecting the light intensity comprises measuring a light reflectivity of the test strip.

17. The method of claim 15 including determining a ratio of the light intensity of each measurement zone and the baseline.

18. The method of claim 7, wherein generating the baseline for each detection zone includes interpolating between the beginning and ending boundary of each measurement zone using a straight line function.

19. The method of claim 7, wherein a processor and memory resources is coupled to a first sensor to detect the detection signals in each detection zones, and wherein the processor and memory resources generates the baseline in each measurement zone.

20. The method of claim 19, wherein first sensor is an optical sensor.

21. The method of claim 19, further including initiating timing of the

lateral flow assay upon detecting a sample deposited on the test strip.

22. The method of claim 21, wherein an automatic starting trigger coupled to the processor and memory resources detects the sample deposited on the test strip.

23. The method of claim 22, including the step of measuring a change using a physical property of the sample to initiate timing the lateral flow assay.

24. The method of claim 22, wherein the physical property of the sample being measured includes an electric field arising from the test strip containing the sample.

25. The method of claim 22, wherein the physical property of the sample being measured includes the surface tension of the sample on the test strip.

26. The method of claim 22, wherein the physical property of the sample being measured includes conductivity of the sample on the test strip.

27. The method of claim 22, wherein the sample is detected by an optical sensor coupled to the automatic starting trigger.

28. The method of claim 21, further comprising:

a. providing a pair of conducting leads in proximity to an area of the test strip where the sample is deposited;

b. applying an electrical potential across the pair of conducting leads to create an electrical field there between;

c. introducing a sample into the electrical field to affect a change in the electrical field, the sample being spaced from the electrical leads; and

d. initiating timing of the lateral flow assay upon detecting the change in the electrical field.

29. The method of claim 21, wherein the processor and memory

resources initiates a timer for analyzing the lateral flow assay once the automatic starting trigger detects the sample of the test strip.

30. The method of claim 21, wherein:

a housing contains the processor and memory resources, the automatic starting trigger, and the first sensor; and

the optical sensor measures reflectivity of the test strip.

31. The method of claim 19, wherein the processor and memory resources stores an assay matrix for a plurality of assays.

32. The method of claim 31, wherein the assay matrix includes a plurality of parameters for performing the multiple lateral flow assays, including parameters for incubation time and temperature control of the lateral flow assay.

33. The method of claim 32, wherein the assay matrix may be reconfigured by inputting information into the processor and memory resources.

34. The method of claim 32, wherein:

the test strip is contained within a cartridge having sensory codes;

the housing includes a second sensor for reading the sensory codes; and

a second sensor inputs information from the sensory codes to select assays from the assay matrix.

35. The method of claim 34, wherein the sensory codes are bar codes, and the second sensor is a bar code reader.

36. The method of claim 19, further comprising heating the test strip inside a housing with a heater element, the heater element being coupled to the processor and memory resources to control temperature and incubation time.

37. The method of claim 7, including:

implementing an assay matrix in a processor and memory resources, the assay matrix containing a plurality of parameters for performing the lateral flow assay;

inserting the test strip into the processor and memory resources; and

controlling the lateral flow assay with the parameters of the assay matrix.

38. The method of claim 34, wherein the assay matrix is reconfigurable with information transferred from a remote computer system.

39. A method for performing a lateral flow assay, comprising the steps of:

a. providing a test strip on a cartridge, the test strip including a first analyte binding agent coupled to a detection agent and a second analyte binding agent;

b. depositing a sample on an application region of the test strip wherein at least a portion of the sample binds to the first analyte binding agent coupled to the detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow to a first detection zone that includes a first measurement zone, at least a portion of the first analyte binding agent complex binding to the second analyte binding agent in the first measurement zone to form a second complex;

c. detecting a first signal intensity in the first detection zone;

d. generating a baseline of a signal intensity from the first detection zone; and

e. quantifying a value of the first signal intensity representative of the second complex with respect to the baseline.

40. The method of claim 39, wherein the step of generating the baseline comprises determining a background reflectance of the test strip.

41. The method of claim 39, wherein the baseline for the first measurement zone is defined by interpolating between a value of a beginning and an ending boundary outside of the first measurement zone but inside the first detection zone.

42. The method of claim 39, wherein the step of detecting the first signal intensity in the first detection zone includes detecting a light intensity of the first detection zone.

43. A method for performing a lateral flow assay, comprising:

a. providing a test strip on a cartridge, the test strip including a first analyte binding agent coupled to a detection agent and a second analyte binding agent;

b. depositing a sample on an application region of the test strip wherein at least a portion of the sample binds to the first analyte binding agent coupled to the detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow past a first detection zone having a first measurement zone and to a second detection zone that includes a second measurement zone, at least a portion of the first analyte binding agent complex binding to the second analyte binding agent in the second measurement zone to form a second complex;

c. detecting a second signal intensity in the second detection zone;

d. generating a baseline of a signal intensity from the second detection zone; and

e. quantifying a value of the second signal intensity representative of the second complex with respect to the baseline.

44. The method of claim 43, wherein at least a portion of the first analyte binding agent complex binds to the second analyte binding agent in the first measurement zone to form a second complex.

45. The method of claim 44, wherein the baseline for the second measurement zone is defined by interpolating between a value of a beginning and an ending boundary outside of the second measurement zone but inside the second detection zone.

46. The method of claim 43, wherein the step of detecting the second signal intensity in the second detection zone includes detecting a light intensity for the second detection zone.

47. A method for performing a lateral flow assay, comprising:

a. providing a test strip on a cartridge, the test strip including a first analyte binding agent coupled to a detection agent and a second analyte binding agent;

b. depositing a sample on an application region of the test strip wherein at least a portion of the sample binds to the first analyte binding agent coupled to a detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow past a first and second detection zone having a first and second measurement zone respectively, and to a third detection zone that includes a third measurement zone, at least a portion of the first analyte binding agent complex binding to the second analyte binding agent in the third measurement zone to form a second complex;

c. detecting a third signal intensity in the third detection

zone;

d. generating a baseline of a signal intensity from the third detection zone; and

e. quantifying a value of the third signal intensity representative of the second complex with respect to the baseline.

48. The method of claim 47, wherein at least a portion of the first analyte binding agent complex binds to the second analyte binding agent in the first measurement zone to form a second complex.

49. The method of claim 48, wherein at least a portion of the first analyte binding agent complex binds to the second analyte binding agent in the second measurement zone to form a second complex.

50. The method of claim 47, wherein the baseline for the third measurement zone is defined by interpolating between a value of a beginning and an ending boundary outside of the third measurement zone but inside the third detection zone.

51. The method of claim 47, wherein the step of detecting the third signal intensity in the third detection zone includes detecting a light intensity for the third detection zone.

52. The method of claim 47, wherein the step of quantifying a value of signal intensity in each measurement zone with respect to the baseline includes evaluating a ratio of the intensity of the respective detection signals over the baseline for each detection zone.

53. A method for performing a lateral flow assay, comprising the steps of:

a. applying an electrical potential across a pair of spaced apart electrical leads to create an electrical field;

b. introducing a sample into the electrical field to induce a change in the electrical field, the sample being spaced from the spaced apart electrical leads; and -

c. initiating timing of the lateral flow assay upon detecting the change in the electrical field.

54. The method of claim 53, wherein the step of introducing the sample into the electrical field includes depositing the sample on a test strip in sufficient proximity to the electrical leads to affect the electrical field.

55. The method of claim 54, wherein the electrical leads form a capacitor having a dielectric layer, and wherein the dielectric layer changes when the test strip receives the sample.

56. The method of claim 53, wherein the step of initiating the lateral flow assay includes initiating a processor coupled to the electrical leads to control the lateral flow assay.

57. The method of claim 54, wherein the spaced apart electrical leads comprise a pair of co-planar plates aligned in sufficient proximity to the test strip to detect a change in a dielectric constant between the coplanar plates and the test strip upon depositing the sample on the test strip.

58. The method of claim 53, including the step of completing the performance of the lateral flow assay after an incubation time initiated by introducing the sample into the electric field.

59. The method of claim 53, further comprising:

a. providing a test strip on a cartridge, the test strip including a first analyte binding agent coupled to a detection agent and a second analyte binding agent, the test strip being in sufficient proximity to the electrical leads to affect the electrical field;

b. depositing a sample on an application region of the test

strip to induce the change in the electric field, wherein at least a portion of the sample binds to the first analyte binding agent coupled to the detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow to a first detection zone that includes a first measurement zone, at least a portion of the first analyte binding agent complex binding to the second analyte binding agent in the first measurement zone to form a second complex;

c. detecting a first signal intensity in the first detection zone;

d. generating a baseline of a signal intensity from the first detection zone; and

e. quantifying a value of the first signal intensity representative of the second complex with respect to the baseline.

60. The method of claim 59, including the step of completing the performance of the lateral flow assay after an incubation time initiated by introducing the sample into the electric field to affect the change in the electric field.

61. The method of claim 60, wherein the incubation time is provided by an assay matrix stored in a processor and memory resources coupled to the electrical leads to control the lateral flow assay.

62. The method of claim 61, wherein the processor and memory resources initiates a timer for analyzing the lateral flow assay upon receiving a signal detecting the change in the electrical field from introducing the sample onto the test strip.

63. A method for performing a lateral flow assay, comprising:

a. depositing a sample on a test strip of a cartridge at an application region of the test strip, the test strip including a first detection zone with a first measurement zone;

b. inserting the cartridge in a housing having a processor and memory resources for storing a plurality of assay tables;

c. selecting a first assay table from a plurality of assay tables to perform the lateral flow assay on the test strip;

d. detecting an intensity of a first detection signal arising from the first detection zone of the test strip that includes the first measurement zone; and

e. quantifying a value of signal intensity for the first detection signal using a parameter from the assay table selected from the plurality of assay tables.

64. The method of claim 63, wherein at least a portion of the sample binds to a first analyte binding agent coupled to a detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow to the first detection zone, and wherein at least a portion of the first analyte binding agent complex binds to the second analyte binding agent in the first measurement zone to form a second complex.

65. The method of claim 63, wherein at least a portion of the sample binds to a first analyte binding agent coupled to a detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow past the first detection zone and to a second detection zone that includes a second measurement zone, at least a portion of the first analyte binding agent complex binding to the second analyte binding agent in the second measurement zone to form a second complex, and the method includes the step of selecting the assay table from the plurality of assay tables to perform the assay on the test strip;

detecting an intensity of a second detection signal arising

from the second detection zone of the test strip that includes the second measurement zone; and

quantifying a value of signal intensity for the second detection signal using a parameter from the assay table selected from the plurality of assay tables.

66. The method of claim 65, wherein at least a portion of the first analyte binding agent complex binds to the second analyte binding agent in the first measurement zone to form a second complex.

67. The method of claim 63, wherein at least a portion of the sample binds to a first analyte binding agent coupled to a detection agent to form a first analyte binding agent complex, the first analyte binding agent complex moving by lateral flow past the first detection zone and a second detection zone having a second measurement zone, and to a third detection zone that includes a third measurement zone, at least a portion of the first analyte binding agent complex binding to the second analyte binding agent in the third measurement zone to form a second complex, and the method includes the step of selecting the assay table from the plurality of assay tables to perform the assay on the test strip;

detecting an intensity of a third detection signal arising from the third detection zone of the test strip that includes the third measurement zone; and

quantifying a value of signal intensity for the third detection signal using a parameter from the assay table selected from the plurality of assay tables.

68. The method of claim 67, wherein at least a portion of the first analyte binding agent complex binds to the second analyte

binding agent in the first measurement zone to form a second complex.

69. The method of claim 67, wherein at least a portion of the first analyte binding agent complex binds to the second analyte binding agent in the second measurement zone to form a second complex.

70. The method of claim 63, wherein the plurality of assay tables may be reconfigured by transferring information into the processor and memory resources through an input device.

71. The method of claim 63, wherein the plurality of assay tables may be reconfigured by transferring information into the processor and memory resources through an optical code on the cartridge.

72. The method of claim 63, wherein the parameters included in the first assay table include an assay time for how long the lateral flow assay is performed.

73. The method of claim 63, wherein the parameters included in the first assay table for use with the step of quantifying the value of signal intensity for the first measurement zone includes a method selection parameter for receiving an input that selects a method for quantifying the value of the detection signal for an output.

74. The method of claim 63, wherein the parameters included in the assay table include an assay temperature parameter for heating the sample to a predetermined temperature.

75. The method of claim 63, wherein the processor receives a signal from an autostart trigger to initiate the lateral flow assay.

76. The method of claim 65, wherein the step of quantifying a value of signal intensity for the first, second, and third measurement

zones includes evaluating the intensity of the detection signal for the corresponding detection zone with respect to a baseline.

77. The method of claim 76, wherein the baseline is generated from the signal intensity for first, second, and third detection zones.

78. An apparatus for performing a lateral flow assay, comprising:

a housing having a receptacle for retaining a test strip that receives a sample, said test strip including a first detection zone with a first measurement zone comprising a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip;

a sensor for detecting a first detection signal arising from the test strip; and

a processor and memory resources that generates a baseline for the first measurement zone by interpolating between values of the first detection signal outside of the first measurement zone and inside of the first detection zone.

79. The apparatus of claim 78, wherein:

the test strip includes a second detection zone with a second measurement zone, the second measurement zone comprising a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip;

the sensor detects a second detection signal arising from the test strip; and

the processor and memory resources generates the baseline for the second measurement zone by interpolating between values of the second detection signal outside of the second measurement zone and inside of the second detection zone.

80. The apparatus of claim 79, wherein:

the test strip includes a third detection zone with a third measurement zone, the third measurement zone comprising a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip;

the sensor detects a third detection signal arising from the test strip; and

the processor and memory resources generates the baseline for the third measurement zone by interpolating between values of the detection signal outside of the third measurement zone and inside of the third detection zone.

81. The apparatus of claim 80, wherein the processor and memory resources executes code for generating a baseline that locates a beginning boundary and an ending boundary for each measurement zone on the test strip.

82. The apparatus of claim 80, wherein the processor and memory resources executes code for quantifying the detection signal in each measurement zone with respect to the baseline.

83. The apparatus of claim 80, wherein the processor and memory resources executes code for analyzing the lateral flow assay by evaluating the first detection signal on a curve defined by the second and third detection signals.

84. The apparatus of claim 80, wherein the first measurement zone is an analyte binding zone that receives an analyte from the sample, and the second and third measurement zones are each a control zone formed from combining a control agent and a control binding agent on the test strip after the sample is deposited on the test strip.

85. The apparatus of claim 84, wherein the sensor is an optical

sensor for detecting a reflection from each of the first, second, and third detection zones, and wherein the baseline represents an average reflection of the test strip excluding the measurement zones.

86. The apparatus of claim 85, wherein the optical sensors are coupled to the processor and memory resources via an analog-digital converter.

87. The apparatus of claim 85, wherein the processor and memory resources executes code for quantifying a first, second, and third reflection signal by determining a difference between the reflection of each measurement zone and the respective baseline.

88. The apparatus of claim 87, wherein memory resources store a plurality of assay tables accessible to the processor, and the processor executes code for quantifying the detection signal of each measurement zone by selecting an assay table from the plurality of assay tables.

89. The apparatus of claim 88, wherein the processor receives input to select the assay table from the plurality of assay tables.

90. The apparatus of claim 89, wherein each assay tables stores a plurality of parameters including an assay time parameter for controlling how long the lateral flow assay selected is performed.

91. An apparatus for performing a lateral flow assay, comprising:

a pair of spaced apart electrical leads contained within a receptacle of a housing, the electrical leads receiving an electrical potential to create an electrical field; and

a test strip contained within the receptacle, the test strip being in sufficient proximity to the electrical leads to induce a change in the electrical field upon receiving a sample.

92. The apparatus of claim 91, wherein the electrical leads form a capacitor having a dielectric layer, and wherein the dielectric layer changes when the test strip receives the sample.

93. The apparatus of claim 92, wherein a processor and memory resources for controlling the lateral flow assay is coupled to the electrical leads and initiates timing the lateral flow assay when the test strip receives the sample.

94. The apparatus of claim 93, wherein the electrical leads comprise a pair of co-planar plates aligned in sufficient proximity to the test strip to detect a change in a dielectric constant between the coplanar plates and the test strip when the test strip receives the sample.

95. The apparatus of claim 94, wherein the processor and memory resources analyzes the lateral flow assay after an incubation time that is initiated by introducing the sample into the electric field.

96. The apparatus of claim 95, wherein:

the test strip includes a detection zone with a measurement zone, wherein the first measurement zone comprises a concentration of compounds that affect an intensity of a signal arising from the test strip, the compounds being formed after the sample is deposited on the test strip,

the processor and memory resources executes code for generating a baseline for the first measurement zone, and for quantifying a value of signal intensity for the first detection zone with respect to the baseline; and

a first sensor detects the intensity of the signal arising from the first detection zone.

97. The apparatus of claim 96, wherein the incubation time is provided by an assay matrix stored in the processor and memory resources.